

REMARKS/ARGUMENTS

Claims 14, 15, 18 through 20, 22, 23, 32 through 34, 36 through 43 and 45 through 51 are pending in the application

No amendments have been made at this time.

Applicant respectfully requests that the following remarks be considered in view of the Office Action made Final and the Advisory Action.

Rejection of Claims 14, 15, 18 through 20, 22, 23, 32 through 34, 36 through 43 and 45 through 51 Under 35 USC § 103(a)

Claims 14, 15, 18 through 20, 22, 23, 32 through 34, 36 through 43 and 45 through 51 stand rejected under 35 USC 103(a) as being unpatentable over U.S. Patent Publication No. 2005/0025756 Erwin (hereinafter "Erwin") further in view of Soft Gel Technologies, Inc. EP 888774 (hereinafter "Soft Gel") and U.S. Patent Publication No. 2004/0001874 Davidson et al. (hereinafter "Davidson"). Applicant respectfully traverses the rejection for at least the following reasons.

To begin, the present invention pertains to a soft gelatin capsule that includes coenzyme Q-10 solubilized (dissolved) in limonene. The present invention also pertains to packaged nutraceuticals for the administration of solubilized coenzyme Q-10 in a soft gelatin capsule. This is the crux of the invention.

The references of record will now be addressed.

Erwin, to some degree, discloses the use of monoterpenes, such as limonene to dissolve coenzyme Q-10. The formulations Erwin discloses are liquid formulations. Erwin goes on to explicitly describe how the liquid formulations could be delivered by either inhalation, oral, intramuscular injection, intravenous (IV)-drip, lingual, gum, sub-lingual, nasal, anal, percutaneous transdermal absorption, or transdermal patch.

Erwin specifically fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art that a liquid composition of coenzyme Q-10 and limonene could be formulated into ANY type of a capsule, let alone a soft gelatin capsule. Erwin simply fails to appreciate that the liquid formulation could be administered in such a fashion. Erwin is completely devoid of any teaching or suggestion, or providing any motivation or an expectation of success to a person having ordinary skill in the art to prepare a soft gelatin capsule that would encapsulate solubilized coenzyme Q-10.

Soft Gel fails to remedy the deficiencies of Erwin, alone or in combination.

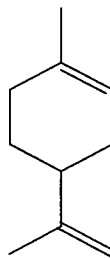
Soft Gel discloses use of rice bran oil or Vitamin E to suspend coenzyme Q-10 in the carrier (rice bran oil or Vitamin E), which is formulated, into a soft gelatin capsule. Soft Gel does not teach or suggest that the rice bran oil or Vitamin E solubilizes (dissolves) coenzyme Q-10.

Soft Gel is completely devoid of any teachings of any carrier other than rice bran oil or Vitamin E. In fact Soft Gel doesn't provide any teaching or suggestion, an expectation of success or any motivation to a person having ordinary skill in the art to try any other carriers. Therefore, the teachings of Soft Gel are very limited in this respect.

Soft Gel fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art to select a monoterpene, such as limonene, as a carrier *for any ingredient*.

Moreover, Soft Gel fails to teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art that limonene would be a good solubilizing agent for coenzyme Q-10. A fair reading of Soft Gel would not provide any teaching, suggestion or motivation to a person having ordinary skill in the art to substitute rice bran oil or Vitamin E with anything other than rice bran oil or Vitamin E.

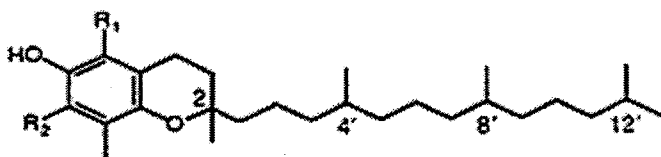
Limonene, Vitamin E and rice bran oil chemically dissimilar in chemical composition.



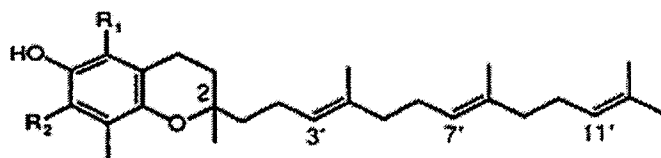
Limonene is a monocyclic terpene having the formula

Limonene, therefore, is a an unsaturated cyclic hydrocarbyl. It is completely devoid of any other functionality other than two degrees of unsaturation.

Vitamin E is a mixture of four different tocopherols (α -, γ , δ , and β -tocopherols) and four corresponding tocotrienols:



R ¹	R ²	
CH ₃	CH ₃	α -Tocopherol
CH ₃	H	β -Tocopherol
H	CH ₃	γ -Tocopherol
H	H	δ -Tocopherol



R ¹	R ²	
CH ₃	CH ₃	α -Tocotrienol
CH ₃	H	β -Tocotrienol
H	CH ₃	γ -Tocotrienol
H	H	δ -Tocotrienol

The typical composition of rice bran oil is 81.3-84.3% triglycerides, 2-3% diglycerides, 5-6% monoglycerides, 2-3% free fatty acids, 0.3% waxes, 0.8% glycolipids, 1.6% phospholipids, and 4% unsaponifiables. The fatty acid components of the glycerides are myristic, palmitic, stearic, oleic, linoleic, linolenic, arachidic, and behenic acids.

As should be noted, limonene has no carboxylic acid (or esters), no phenolic and no ether components as do the fatty acids of rice bran oil, and Vitamin E (respectively). Moreover,

Vitamin E and rice bran oil are combinations of components, whereas limonene is a single material.

There is simply no teaching or suggestion, expectation of success or motivation provided to a person having ordinary skill in the art to interchange such carriers, having vastly different physical properties in terms of functionality and/or polarity in view of the differences between limonene versus rice bran oil or Vitamin E.

Soft Gel fails to remedy the deficiencies of Erwin. Soft Gel only discloses use of plant oils to formulate coenzyme Q-10. Additionally, it is not clear whether the oils solubilize the coenzyme Q-10, or merely suspend the coenzyme Q-10 in an oil phase. In contrast, limonene solubilizes the coenzyme Q-10.

There is a disconnect here between the present rejection and the present invention. There simply is no teaching or suggestion, no motivation or an expectation of success to cause a person having ordinary skill in the art to substitute limonene for rice bran oil or Vitamin E and then formulate this new formulation into a soft gelatin capsule.

Again Erwin fails to teach, suggest, and provide any motivation or an expectation of success to a person having ordinary skill in the art that a limonene formulation could be encapsulated into a soft gel capsule.

Soft Gel fails to teach or suggest that limonene could be substituted for rice bran oil or Vitamin E or vice versa.

Therefore, neither Erwin nor Soft Gel, alone or together, teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art to incorporate solubilized coenzyme Q-10 in limonene into a soft gelatin capsule.

Davidson does not remedy the deficiencies of either Erwin or Soft Gel, alone or in combination.

Davidson teaches much the same as Soft Gel, in that coenzyme Q-10 can be formulated in fish oil in a soft gelatin capsule. Again, it is not known whether the fish oil solubilizes the coenzyme Q-10 or merely suspends the coenzyme Q-10.

Fish oil has as its major components, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA). These are polyunsaturated fatty acids or glycerides thereof. Again, these compounds contain carboxylic acids (or esters) and do not have similar structural characteristics akin to that of limonene. Again, fish oil is a combination of at least two (2) components, whereas limonene is a single material. Limonene is an unsaturated cyclic hydrocarbon. It is completely devoid of any other functionality other than two degrees of unsaturation.

Davidson is completely devoid of teaching or suggestion, providing any motivation or an expectation of success to a person having ordinary skill in the art that any carrier other than fish oil would be a suitable substitute to solubilize coenzyme Q-10.

As noted above, the constitution of fish oil and limonene are chemically dissimilar.

There is no teaching or suggestion, expectation of success or motivation that a person having ordinary skill in the art would consider that limonene and fish oil could be interchangeable as a carrier for coenzyme Q-10. There is simply no teaching or suggestion, expectation of success or motivation such that a person having ordinary skill in the art would rely on Davidson to substitute limonene for fish oil.

None of the references, alone or in combination, teach or suggest, provide any motivation or an expectation of success to a person having ordinary skill in the art to incorporate solubilized coenzyme Q-10 in limonene into a soft gelatin capsule.

Additionally, it appears that the arguments within the Office Action made Final and Advisory action essentially take the position that solubilization of any ingredient in any carrier encapsulated in a soft gelatin capsule would be obvious. This is not the correct legal standard.

This argument equates to a determination that it would be obvious to provide a carrier and any ingredient (in the future) in a soft gelatin capsule. Again, this is not the correct legal standard. The argument is not sustainable, without the requisite teaching, suggestion, or motivation provided in the reference(s) to a person having ordinary skill in the art as explained by the following paragraphs.

In *In re Johnston* F. 3d 1381 (Fed. Cir. 2006), the Federal Circuit provided an excellent review of its string of precedents concerning the standard for combining references in an obviousness rejection. The court noted in *Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376, 1385 (Fed. Cir. 2001), that

In holding an invention obvious in view of a combination of references, there must be some suggestion, motivation, or teaching in the prior art that would have led a person of ordinary skill in the art to select the references and combine them in the way that would produce the claimed invention.

The court went on to state that in *In re Dance*, 160 F.3d 1339, 1343 (Fed. Cir. 1998) that

When the references are in the same field as that of the applicant's invention, knowledge thereof is presumed. However, the test of whether it would have been obvious to select specific teachings and combine them as did the applicant must still be met by identification of some suggestion, teaching, or motivation in the prior art, arising from what the prior art would have taught a person of ordinary skill in the field of the invention.

The court went on to reiterate that *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988)

...there must be some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references...

Lastly, and most pointedly, *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985) instructs that

When prior art references require selective combination by the court to render obvious a subsequent invention, there must be some reason for the combination other than the hindsight gleaned from the invention itself.

It appears that the Office Action made Final has done just that; used a hindsight analysis to arrive at the presently claimed invention. Based on the references of record, there simply is no reason to substitute limonene as a carrier for coenzyme Q-10 and place the solubilized coenzyme Q-10 (that is in limonene) into a soft gelatin capsule. What is missing is why, in view of the teachings of Soft Gel and Davidson which focus on carriers that include chemical polar functionality (carboxylic esters, carboxylic acids, and/or ethers), one skilled in the art would select limonene as a replacement and take that new combination and place it in a soft gelatin capsule.

It is believed that all of the issues raised in this rejection have been addressed herein. Should the Examiner maintain any of the rejections of any of the pending claims, it is respectfully requested that it be pointed out with particularity how the cited reference(s) meet each and every term of each claim with respect to which rejection is maintained, and if the rejection is based on obviousness, identification of the specific motivation, suggestion or teaching in the prior art for combining elements in the specific combination of the invention.

Reconsideration and withdrawal of the rejection is respectfully requested.

CONCLUSION

Please charge our Deposit Account No. 04-1420 for the fee of One Month Extension in the amount of \$60.00. However, if further payment is needed the Commissioner is hereby authorized to charge our Deposit Account No. 04-1420 and notify us of the same.

In view of the above, Applicant respectfully submits that the present application is in condition for allowance. Reconsideration of the present application and a favorable response are respectfully requested.

If a telephone conference would be helpful in resolving any remaining issues, please contact the following at 612-340-8819.

Respectfully submitted,

DORSEY & WHITNEY LLP

Customer Number 25763

Date: August 31, 2006

By: 

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